UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,847	07/10/2003	Hazel Judith Bardsley	GJE-6757C1	7988

23557 7590 11/26/2007

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
SOROUSH, LAYLA	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
11/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,847	BARDSLEY ET AL.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/11/07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed September 11, 2007 presents remarks and arguments submitted to the office action mailed April 11, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-13 over Ninomiya et al. (US Pat. No. 4,695,568 –IDS), in view of McInally et al. (PCT/SE98/00641 English equivalent US Pat. No. 6303613) and Kelley et al. (US PAT No. 5708033) is persuasive. Therefore, the rejection is withdrawn.

Applicant's arguments over the Obvious Double Patenting rejection over co-pending Application No. 10/525532 is not persuasive. The ODP rejection made will be withdrawn once the Terminal Disclaimer is filed. However, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 101 rejection of claims 5-11 over co-pending Application No. 10/519594 is not persuasive. Thus, the rejection is maintained for the reasons of record.

In view of applicant's arguments to the claims, the following new rejections are made:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (Effects of Acute and Chronic Administration of MCI-225, a New Selective Noradrenaline Reuptake Inhibitor With 5-HT3 Receptor Blocking Action, on Extracellular Noradrenaline Levels in the Hypothalamus of Stressed Rats. Japan. Journal of Pharmacology.83.pages 31-38.200) and Ninomiya et al. (US Pat. No. 4,695,568 – previously presented) in view of Davies et al. (US Pat. No. 6,008,227 – previously presented).

Wu et al. teaches (4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine hydrochloride monohydrate (MCI-225) is a psychoactive compound that is a selective noradrenaline (norepinephrine) reuptake inhibitor with 5-HT3 receptor blocking action which has been reported to have antidepressant activity.

Ninomiya et al. is solely used to show that the general teaching of administration of the (4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine hydrochloride monohydrate to a patient renders obvious the administration to both male and female patients. Hence, meeting the limitation of claim 9.

Wu et al. does not specifically teach the compound to treat nociceptive or neuropathic pain, irritable bowel disorder, nor fibromyalgia.

However, Davies et al. teaches, in the Background of the Invention, that two important central nervous system neurotransmitters are serotonin (5-HT) and dopamine (DA). Together with norepinephrine and epinephrine, these neurotransmitters comprise the group of agents known as the monoamines. Either 5-HT or DA have been

implicated in a variety of disorders, including depression, Parkinsons disease, ADD, obesity and cocaine addiction. Antidepressants inhibit monoamine uptake mechanisms, but differ in selectivity between the dopamine, 5-HT and norepinephrine transporters. Other syndromes also respond to antidepressant drugs. These include (1) severe anxiety syndromes characterized by panic reactions, and (2) obsessive-compulsive disorder, both of which seem most likely to respond to 5-HT selective agents. Monoamine uptake blockers have also been useful in treatment of chronic pain (nociceptive pain), neuralgias (neuropathic pain), migraine, sleep apnea, fibromyalgia, and irritable bowel syndrome (functional bowel disorder) (column 1 lines 60-67 and column 2 lines 1-2), as recited in claims 3-5, 7, and 12.

Therefore, it would have been obvious to one of ordinary skill in the art to use a psychoactive compound that is a selective noradrenaline (norepinephrine) reuptake inhibitor with 5-HT3 receptor blocking action which has been reported to have antidepressant activity in treating nociceptive or neuropathic pain, irritable bowel syndrome, and fibromyalgia. The motivation to use 4-(2-Flourophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine to treat nociceptive or neuropathic pain, irritable bowel syndrome, and fibromyalgia is because the teachings in Davies et al. that antidepressant agent used to inhibit monoamine uptake mechanisms are also useful in treating chronic pain, neuralgias, migraine, sleep apnea, fibromyalgia, and irritable bowel syndrome (functional bowel disorder). The skilled artisan would have reasonable expectation of treating nociceptive or neuropathic pain, irritable bowel

syndrome(functional bowel disorder), and fibromyalgia using the antidepressant drug 4-(2-Flourophenyl)-6-methyl-2-(1- piperazinyl)thieno[2,3-D]pyrimidine.

Additionally, because the reference teaches the genus irritable bowel syndrome, the species diarrhea-predominant irritable bowel syndrome, and alternating constipation/diarrhea of claims 8, 10, and 11 are rendered obvious by the teachings of the prior art.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 5-11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of copending Application No.10519594. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 30, 31, and 35 of co-pending application no. 10/525532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the copending application is drawn to a method for the treatment of a condition selected from the group consisting of fibromyalgia; Parkinson's disease; stroke; and schizophrenia; wherein the treatment comprises administering, to an individual in need of such treatment, (4-(2-Flourophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine or a salt thereof whereas the invention herein is drawn to a a method for the treatment of fibromyalgia which comprises administering to a patient an effective amount of 4-(2-Flourophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine.

The invention is rendered obvious because the claims of the copending application teach a genus of diseases treated by the same composition. The copending application specifically recites the treatment of the condition fibromyalgia.

Response to Arguments

Applicant's arguments September 11, 2007 have been fully considered but they are not persuasive for the reasons set forth below.

Applicant's arguments that McInally et al. compounds have the ability to inhibit nitric oxide synthase; which is not even a component of MCI-225's known activity; and that, the useful therapeutic activity of MC-225 is attributed to noradrenaline uptake inhibition, serotonin 5-HT3 antagonism and serotonin uptake inhibition is persuasive. In view of the new ground(s) of rejection the applicant's arguments are moot.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER